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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/718,262	11/20/2003	Paul B. McCray JR.	17023-035US1	2088

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EXAMINER	
GUZO, DAVID	

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 11/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/718,262	MCCRAY ET AL.	
	Examiner	Art Unit	
	David Guzo	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 September 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) *15-17, 27-28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,5-7,10,11,14,18,19 and 22-26* is/are rejected.

7)☒ Claim(s) *3,4,8,9,12,13,20 and 21* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *11/10/03* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1/6/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Petition Decision*.

Detailed Action

Election/Restriction

Applicant's election without traverse of Group I, Claims 1-14 and 18-26 in the reply filed on 9/21/05 is acknowledged.

Claims 15-17 and 27-28 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 9/21/05.

Petition under 37 CFR 1.84(a)(2)

The Petition for acceptance of Color Drawings under 37 CFR 1.84(a)(2) is denied because said Petition does not comply with 37 CFR 1.84(a)(iv). Specifically, the petition is not accompanied by an amendment to the specification indicating the presence of color drawings. The following text must be present in the specification:

The patent or application file contains at least one drawing executed in color. Copies of this patent or patent application publication with color drawing(s) will be provided by the Office upon request and payment of the necessary fee.

35 USC 102 Rejections

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 10 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Beyer et al.

Applicants claim a pseudotyped retrovirus virion comprising a Lymphocytic Choriomeningitis Virus (LCMV) strain WE-54 envelope glycoprotein or an isolated vector comprising a nucleic acid encoding an envelope glycoprotein from LCMV strain WE-54 or a kit comprising said vector and a transgene vector comprising a functional and compatible packaging signal, the transgene vector being incapable by itself of causing a cell transfected by the transgene vector to encapsulate the RNA form of the transgene vector into a retroviral particle comprising an LCMV-WE54 envelope glycoprotein. A kit comprising the recited components is interpreted here as the separate components contained in separate containers.

Beyer et al. (cited by applicants, J. Virol., Feb. 2002, Vol. 76, No. 3, pp. 1488-1495, see whole article, particularly the Abstract; first eight paragraphs of the "Materials and Methods" section on p. 1489; Tables 1, 3 and 5 and Fig. 1) recites isolated and purified retroviral (lentiviral) virions (vectors) pseudotyped with a LCMV WE-54 (also known as the HP1 strain) envelope. With regard to the kit claim, Beyer et al. recites LCMV envelope pseudotyped retroviral vectors and a transgene vector (containing a GFP transgene) wherein said transgene vector is incapable by itself of causing a cell transfected by the transgene vector to encapsulate the RNA form of the vector into a retroviral particle comprising the LCMV WE-54 envelope glycoprotein. Since the components of the vector system recited by Beyer et al. must be separate at some point

and be stored in receptacles prior to being used, it must be considered that Beyer et al. teaches the claimed kit and invention.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 5-7, 10, 11, 14, 19 and 25-26 are rejected under 35 U.S.C. 102(e) as being anticipated by Von Laer et al.

Applicants' invention is as described in the above 35 USC 102(b) rejection. Additionally, applicants recite a pseudotyped feline immunodeficiency virus (FIV) virion comprising a envelope glycoprotein from Lymphocytic Choriomeningitis Virus (LCMV) (WE-54) as well as a method of producing in the form of infectious particles a transgene vector containing a remedial gene, comprising transfecting a cell with (a) a packaging vector; (b) a vector comprising a nucleic acid encoding a LCMV envelope glycoprotein from strain WE-54 and (c) a transgene vector comprising the remedial gene and a functional packaging signal, which by itself is incapable of causing a cell to produce transducing vector particles, wherein the cell produces infectious transducing vector particles comprising the transgene vector in RNA form, Gag protein, a Pol protein, and a

pseudotyped envelope glycoprotein. The pseudotyped virions have an LCMV envelope glycoprotein having a phenylalanine at residue 260.

Von Laer et al. (cited by applicants, US 6,589,763, issued 7/8/03, filed 11/22/2000, see whole document, SEQ ID NO:4; particularly Figs. 1 and 3; columns 3-4; columns 7-9; Examples 1-6) recite a pseudotyped lentiviral virion (which can be a feline immunodeficiency virus (FIV) virion, see column 7, lines 11-32) comprising a envelope glycoprotein from Lymphocytic Choriomeningitis Virus (LCMV) strain WE-54 (also known as HP1) wherein said envelope glycoprotein has a phenylalanine at residue 260, as well as a method of producing in the form of infectious particles a transgene vector containing a therapeutic gene, comprising transfecting a cell with (a) a packaging vector; (b) a vector comprising a nucleic acid encoding a LCMV envelope glycoprotein from strain WE-54 and (c) a transgene vector comprising the therapeutic gene and a functional packaging signal, which by itself is incapable of causing a cell to produce transducing vector particles, wherein the cell produces infectious transducing vector particles comprising the transgene vector in RNA form, Gag protein, a Pol protein, and a pseudotyped envelope glycoprotein. Von Laer et al. therefore teaches the claimed invention.

Claims 1-2, 10-11, 14, 18, 19, 22-26 are rejected under 35 U.S.C. 102(e) as being anticipated by Kaleko et al.

Applicants claim a pseudotyped retrovirus virion comprising a Lymphocytic Choriomeningitis Virus (LCMV) strain WE-54 envelope glycoprotein or an isolated

vector comprising a nucleic acid encoding an envelope glycoprotein from LCMV strain WE-54 or a kit comprising said vector and a transgene vector comprising a functional and compatible packaging signal; the transgene vector being incapable by itself of causing a cell transfected by the transgene vector to encapsulate the RNA form of the transgene vector into a retroviral particle comprising an LCMV-WE54 envelope glycoprotein. Applicants recite a packaging cell line comprising an inducible expression nucleic acid sequence comprising a polynucleotide encoding an LCMV-WE54 envelope glycoprotein (with a phenylalanine at residue 260), a transgene vector comprising a remedial gene, a method for producing infectious viral particles vector containing a remedial gene, comprising transfecting said packaging cell with (a) a packaging vector, and (b) a transgene vector comprising the remedial gene and a functional packaging signal, which by itself is incapable of causing a cell to produce transducing vector particles, wherein the cell produces infectious transducing vector particles comprising the transgene vector in RNA form, a Gag protein, a Pol protein, and a pseudotyped envelope glycoprotein as well as a kit comprising a vector pseudotyped with a LCMV WE54 strain envelope, and a transgene vector comprising a functional and compatible packaging signal, the transgene vector being incapable by itself of causing a cell transfected by the transgene vector to encapsulate the RNA form of the transgene vector into a retroviral particle comprising an LCMV-WE54 envelope glycoprotein.

Kaleko et al. (US 2003/0054548, published 3/20/2003, filed 3/13/2002, see whole document, particularly paragraphs [0006], [0050]-[0052], [0072], Claims 1-12 and Figs. 1 and 3) recites retroviral (lentiviral) vectors pseudotyped with the LCMV HP1 strain

(also known as the WE54 strain which has a phenylalanine at residue 260) envelope, packaging cell lines for generation of said vectors wherein said packaging cell line comprises sequences encoding the packaging proteins gag and pol and a vector comprising the gene encoding the LCMV WE54 (HP1) strain envelope under control of an inducible promoter and a method for producing infectious retroviral vectors comprising transfecting the packaging cell with the vectors encoding the packaging proteins and the LCMV envelope protein as well as a transgene vector (incapable, by itself, of causing the host cell to produce an infectious vector) encoding a therapeutic gene. With regard to the kit claims, since the components of the vector system recited by Kaleko et al. must be separate at some point and be stored in receptacles prior to being used, it must be considered that Kaleko et al. teaches the claimed kit and invention.

Claim 14 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim 14 recites a method of producing infectious viral particles wherein the particles contain a "pseudotyped envelope glycoprotein". However, the claims from which claim 14 depends are limited to an isolated vector comprising a nucleic acid encoding a LCMV envelope glycoprotein, not any envelope glycoprotein, and hence claim 14 is broader in scope that the claims from which it depends.

Claims 3-4, 8-9, 12-13, 20-21 are free of the art because the prior art does not teach or suggest LCMV variant envelopes with a phenylalanine at residue 153. There is no suggestion in the art to substitute a phenylalanine residue for the normal residue at position 153 in a LCMV envelope glycoprotein.

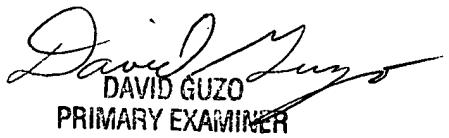
Claims 3-4, 8-9, 12-13 and 20-21 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo, Ph.D., whose telephone number is (571) 272-0767. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D., can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



David Guzo
October 30, 2005